K073478

SEP - 3 2008

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Colleen Boswell - Contact Person
Date Summary Prepared: November 2007

Device Name:

- Trade Name - ***SUPERtorque High-Speed Handpieces***
- Common Name – Dental Handpiece
- Classification Name - Handpiece, Air-Powered, Dental, per 21 CFR § 872.4200

Devices for Which Substantial Equivalence is Claimed:

- Siemens AG (now Sirona), *T1 Control High Speed Dental Handpieces (K965238)*
- DEN-TAL-EZ, Inc., *STAR DENTAL 430 Series High Speed Handpieces (K960719).*

Device Description:

The *SUPERtorque High-Speed Handpieces* are dental handpieces for use by a trained professional in general dentistry. The devices are air-powered handpieces that are re-usable and ergonomically shaped, and are provided both with and without a fiber optic light system. The devices can be sterilized by the steam autoclave method.

Intended Use of the Device:

The *SUPERtorque High-Speed Handpieces* are intended for the removal of carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

Substantial Equivalence:

The *SUPERtorque High-Speed Handpieces* is substantially equivalent to other legally marketed devices in the United States. The intended use of the devices is identical to that of the predicate. The *SUPERtorque High-Speed Handpieces* are substantially equivalent in design, application and function to the *T1 Control High Speed Dental Handpieces* marketed by Siemens AG (now owned by Sirona) and *STAR DENTAL 430 Series High Speed Handpieces* marketed by DEN-TAL-EZ, Inc.

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Submitter:

Sybron Dental Specialties, Inc.
1717 West Collins Drive
Orange, CA 92656
Colleen Boswell - Contact Person
Date Summary Prepared: November 2007

Device Name:

- Trade Name - ***GENTLEpower Handpieces and Attachments***
- Common Name – Dental Handpiece and Accessories
- Classification Name - Handpiece, Air-Powered, Dental, per 21 CFR § 872.4200

Devices for Which Substantial Equivalence is Claimed:

- A-dec/W&H, *Synea Air-Driven Highspeed Handpieces and Attachments (K070663)*

Device Description:

The *GENTLEpower Handpieces and Attachments* are dental instruments for use by a trained professional in general dentistry. The handpieces and attachments are powered by either an air-motor or electric motor. The devices are re-usable and ergonomically shaped, and can be sterilized by the steam autoclave method.

Intended Use of the Device:

The *GENTLEpower Handpieces and Attachments* are intended for the removal of carious material, excess filling material, reducing hard tooth structure, cavity and crown preparation, root canal preparation, finishing tooth preparations, restorations and for polishing tooth.

Substantial Equivalence:

The *GENTLEpower Handpieces and Attachments* are substantially equivalent to other legally marketed devices in the United States. The intended use of the devices is identical to that of the predicate. The *GENTLEpower Handpieces and Attachments* are substantially equivalent in design, application and function to the *Synea Air-Driven Highspeed Handpieces and Attachments* marketed by A-Dec/W&H.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2008

Ms. Colleen Boswell
Vice President, Regulatory Affairs
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K073478
Trade/Device Name: SUPERtorque High-Speed Handpieces and GENTLEpower Handpieces and Attachments
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: II
Product Code: EFB
Dated: August 29, 2008
Received: September 2, 2008

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for //

Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K073478

Indications for Use

510(k) Number (if known):

Device Name: SUPERtorque High-Speed Handpieces

Indications for Use:

The *SUPERtorque High-Speed Handpieces* are intended for the removal of carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations, restorations, and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073478

K073478

Indications for Use

510(k) Number (if known):

Device Name: GENTLEpower Handpieces and Attachments

Indications for Use:

The *GENTLEpower Handpieces and Attachments* are intended for the removal of carious material, excess filling material, reducing hard tooth structure, cavity and crown preparation, root canal preparation, finishing tooth preparations, restorations and for polishing teeth. They are designed for use by a trained professional in the field of general dentistry.

Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

)ivision Sign-Off)
ivision of Anesthesiology, General Hospital
nfection Control, Dental Devices

10(k) Number: K073478